

REMARKS

The Office Action has been carefully reviewed. No claim is allowed. Claims 1 and 6 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The face-to-face interview on May 4, 2005, is gratefully acknowledged. The undersigned wishes to thank the examiner for the courtesies extended at the interview. Previously pending claims 1 and 4 were discussed at the interview, with the undersigned indicating that claim 4 would be cancelled without prejudice, thereby mooted the 35 U.S.C. §112, first paragraph, lack of enablement rejection of claim 4. The discussion and arguments presented at the interview with regard to the lack of enablement rejection of claim 1 is discussed and presented below.

Claim 1 has been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. This rejection is respectfully traversed.

Claim 1 is now amended so that the presently claimed method is only directed towards determining the prognosis of HIV infected individuals who are not yet at the AIDS stage. This is clear from the recitation in claim 1 that the measured anti-tat antibody and p24 protein levels are indicative of either disease

progression or non-progression "towards AIDS", meaning these HIV infected individual do not yet have the symptoms of AIDS.

Furthermore, it was argued that applicants have presented results in Example 1 of the specification, in particular in Tables 2, 3 and 6, and disclosed in the text of Example 1 that anti-tat antibody levels and p24 protein levels are correlated (inversely correlated with each other) with disease progression towards AIDS. The examiner indicated that the non-progressors (NP) should be defined as disclosed in Example 1, page 8, lines 7-12. New claim 6, which is dependent from claim 1, is now added to recite that the HIV infected individual is a non-progressor who has been seropositive for HIV for over eight years, is clinically asymptomatic in the absence of antiretroviral therapy, and does not have a CD4 cell count below $500/\text{mm}^3$, as disclosed in the present specification on page 8, lines 7-12.

The examiner expressed concern at the interview about the correlation between HIV anti-tat levels and p24 antigenemia in the non-progressed non-progressor (NP-NP) versus the progressed non-progressor (NP-P) population. While applicants believe that the experimental results shown in Example 1 of the specification is sufficient to show the inverse correlation between anti-tat antibody level and p24 antigen level and to show its prognostic value for disease progression/non-progression

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towards AIDS, the examiner suggested that either the original raw data of Example 1 be re-packaged to better show the correlation for anti-tat and p24 and/or any additional results that the applicants may have on anti-tat and p24 levels be presented in declaration form for consideration. Applicants intend to present such a declaration and are contemporaneously filing a petition for suspension of action to allow applicants sufficient time to prepare the declaration for submission and consideration by the examiner.


Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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A handwritten signature in black ink, appearing to be "Allen C. Yun", is written over a horizontal line. The signature is stylized with a large loop and a crossbar.

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